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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/027,272	12/21/2001	Stephen L. Crooks	54913US108	3032

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Office of Intellectual Property Counsel
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EXAMINER

HUANG, EVELYN MEI

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 07/29/2002

6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/027,272

Applicant(s)

CROOKS ET AL.

Examiner

Evelyn Huang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-37 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: .

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1. Claims 1-37 are pending.

Priority

2. If applicant desires priority under 35 U.S.C. 119(e) based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph.

The provisional application 60/298768 for which the priority is sought as indicated in the Oath/Declaration is by different inventors and has the title 'Method for the treatment of periodontal disease', which is quite different from the instant 'Sulfonamide and sulfamide substituted imidazoquinolines'. Clarification is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 29-37 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the use of the inventive compounds for inducing biosynthesis of interferon alpha or tumor necrosis factor, does not reasonably provide enablement for the use of the compounds for inducing cytokine biosynthesis and for treating any viral diseases and neoplastic diseases. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

- a. *Nature of the invention.*

The instant invention is drawn to a sulfonamide and sulfamide substituted imidazoquinoline for inducing cytokine biosynthesis, for treating a viral disease and a neoplastic disease in an animal.

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b. *State of the prior art and the level of the skill in the art.*

Certain viral infection is susceptible to replication inhibition by interferon. Synthetic inducers of interferon are known (Fleming, 3692907, column 23, claim 32). Imidazo[4,5-c]quinolin-4-amine derivatives are also known to induce interferon biosynthesis (Gerster, 5266575, columns 9-10, PTO-1449). Certain imidazo[4,5-c] quinoline compounds have been shown to induce TNF and IL-1 production (Testerman, abstract, PTO-1449). Furthermore, at present there is no known umbrella drug that can treat any type of viral and neoplastic disease.

The level of the skill in the cytokine biosynthesis art is high.

c. *Predictability/unpredictability of the art.*

The high degree of unpredictability is well recognized in the cytokine biosynthesis art. A slight change in the structure of the compound would drastically change its biological activity as evidenced in the different values of structurally similar compounds in the interferon bioassay and the different anti-viral activities by the same compounds in the type II Herpes simplex-infected guinea pigs (Gerster, columns 9-10). The effect of a compound on various viruses in an animal is highly unpredictable as illustrated by Fleming, columns 11-18. Structurally similar imidazo[4,5-c] quinoline compounds have different profiles in the induction of the different cytokines (Testerman, page 367, 368, Table 1 and Table 2).

d. *Amount of guidance/working examples.*

The preparation of 231 example compounds has been described. The ability of the example compounds to induce interferon and TNF in human blood cells is shown on pages 92-97 of the specification. No in vivo procedures are described.

e. *Breadth of the claims.*

Applicant's assertion that all the structurally diverse compounds, including those having cycloalkyl, aryl, heteroaryl, heterocyclyl, further substituted with optionally substituted aryl, heteroaryl, heterocyclyl, are effective inducers of all types of cytokines, effective in treating all viral diseases and all neoplastic diseases does not commensurate with the scope of the objective enablement, especially in view of the high degree of unpredictability and the working examples limiting to induction of interferon and TNF, and the fact that at present there is no known umbrella drug effective for treating all viral or neoplastic diseases (paragraphs c, d above).

f. *Quantitation of undue experimentation.*

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Since insufficient guidance and teaching have been provided by the specification (paragraphs c-e above), one of ordinary skill in the art, even with high level of skill, is unable to use the instant compound as claimed without undue experimentation except for using the inventive compounds for inducing the biosynthesis of interferon alpha or tumor necrosis factor alpha in an animal in need thereof.

Double Patenting

4. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-28 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-28 of prior U.S. Patent No. 6331539 (PTO-1449). This is a double patenting rejection.

Conclusion

5. The closest prior art is Nanba (6069149, PTO-1449) wherein an interferon-inducing imidazo[4,5-c]quinoline compound is described. Nanba's compound has an amide with a terminal amino whereas the instant has a sulfonamide or sulfamide as R1. Motivation to modify the prior art compound to arrive at the instant is lacking.

6. No claims are allowed.

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7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Evelyn Huang whose telephone number is 703-305-7247. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on 703-308-4698. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Evelyn Huang

Primary Examiner

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July 24, 2002